

## Portable Device for COVID-19 detection at the Point-of-Care; a Global Diagnostics Approach

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### Abstract:

The EU-funded project **IRIS-COV** aims to deliver a fast and accurate diagnostic solution for **COVID-19 testing at the point of care to address current but also future epidemics at a global level**. The project employs a mature technology based on novel concepts and well-defined delivery and dissemination routes. It also concerns measures and actions for **fast implementation** in hospitals, intensive care units, airports, testing points and even at home, for an immediate impact in public health control.

The work exploits an already developed device prototype (IRIS), specifically designed to perform real time quantitative colorimetric LAMP (qcLAMP). The method has been demonstrated to exhibit enhanced sensitivity and specificity when using both extracted RNA and crude nasopharyngeal samples. Clinical validation with patients' samples showed a sensitivity of 97 and 84% for extracted and unpurified RNA, respectively, and in both cases a specificity of 100%.

Key objectives of the project are to complete validation and certification of the industrially-designed device for two assays, COVID-19 and influenza, as per IVDD (initially) and IVDR (subsequently). Moreover, the robustness, simplicity and cost-effectiveness of the device and method make it suitable for application in developing countries; currently, production and certification with one of the partners in S. Africa is under progress.